# EXHIBIT M

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Northern Division

UNITED STATES OF AMERICA, ex rel.
Sandra Boucher
4420 Norwood Road
Baltimore, Maryland 21218,

and

William Frye
P.O. Box 2434
Columbia, South Carolina 29202,

and

Kimberly Jackson
2417 Georgia Place
Alexandria, Virginia 22311,

Plaintiffs,

v.

Serono Laboratories, Inc.
100 Longwater Circle
Norwell, Massachusetts 02061,

SERVE ON RESIDENT AGENT:
The Corporation Trust
300 E. Lombard Street
Baltimore, Maryland 21201

and

Serono, Inc.
100 Longwater Circle
Norwell, Massachusetts 02061

SERVE ON RESIDENT AGENT:
The Corporation Trust
300 E. Lombard Street
Baltimore, Maryland 21201

Civil Action No.

**CIVIL FALSE CLAIMS ACT COMPLAINT WITH REQUEST FOR JURY TRIAL**

**FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

**DO NOT ENTER IN PUBLIC PACER**
**DO NOT PLACE IN PRESS BOX**

and

The Serono Group
Chemin des Mines 15bis
P.O. Box 54
1211 Geneva 20 -- Switzerland,

Defendants.

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Plaintiff-Relators Sandra Boucher, William Frye, and Kimberly Jackson ("Relators) bring this qui tam action in the name of the United States of America, against defendants Serono Laboratories, Inc. ("Serono"), Serono, Inc. ("SI"), and the Serono Group ("SG"), pursuant to the provisions of the False Claims Act. This is an action to recover damages and civil penalties on behalf of the United States of America arising out of defendants' false and fraudulent billing and claims for payment to the Medicaid program, in connection with the prescription of a drug manufactured by Serono called "Serostim" for AIDS and AIDS-related conditions.

**Jurisdiction and Venue**

1. This action arises under the provisions of Title 31 U.S.C. Section § 3729, et seq., popularly known as the "False Claims Act."

2. Based on the provisions of the False Claims Act, Relators seek through this action to recover damages and civil penalties arising from false and fraudulent claims submitted by defendants in violation of the False Claims Act and law and regulation, governing the payment for and reimbursement by the Medicaid program, for prescription drugs.

3. This Court has jurisdiction over this action pursuant to 31 U.S.C. §§ 3730, 3732(a), and 28 U.S.C. § 1331, because this action arises under the laws of the United States.

4. Venue is proper in the District of Maryland under 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because defendants Serono and SI may be found and do business in the District of Maryland, and many of the acts complained of herein occurred in the District of Maryland, and against defendant SG because the acts complained of by SG had their effect in the District of Maryland.

5. This Court has personal jurisdiction over defendants pursuant to 31 U.S.C. § 3732(a).

**Parties**

6. Serono employed Relator Kimberly Jackson beginning August, 1997 as a Sales Representative in the Virginia area, and promoted her to the position of Regional Director, for states including the State of Maryland. She resigned her position with Serono in September, 1999.

7. Serono employed Relator Sandra Boucher beginning July, 1997 as a Sales Representative in the Baltimore, Maryland area and later promoted her to the position of clinical consultant and regional development specialist sales. She resigned her position with Serono in November, 1999.

8. Serono employed Relator William Frye also beginning July, 1997 as a Sales Representative in the South Carolina and Georgia area. He resigned his position with Serono in November, 1999.

9. Relators have standing to bring this complaint for themselves and on behalf of the United States Government pursuant to 31 U.S.C. § 3730.

10. Serono is headquartered in Norwell, Massachusetts, and is a wholly-owned

subsidiary of the SG, a Swiss corporation. SI is also a subsidiary of SG. According to its web site, the Serono Group in 1999 had $1.054 billion in worldwide sales and a net income of $183.7 million. The Serono Group operates in 45 countries, and its products are sold in over 100 countries. Serostim is one of its four major drug products. Serono sells Serostim throughout the United States, including in Maryland, through a network of sales representatives, who call on physicians and pharmacies.

11. At all times hereinafter mentioned, Serono, SI and SG jointly and severally conspired to submit false statements in connection with the prescription of and sales of Serostim throughout the United States.

**Defendants' Wrongful Acts**

12. Serono participated in the following practices which defrauded the United States through the Medicaid program, submitting false claims to the United States for payment, and resulting in payments to Serono, and indirectly by repatriation of profits through Serono to SI and SG, in violation of the False Claims Act:

a. Provision of inducements to physicians to encourage patients' use of Serostim;

b. Creation of a system that supposedly would "measure" patients' body mass wasting and determine whether they needed Serostim, which Serono encouraged sales representatives to manipulate in order to boost sales artificially, to persons who did not clinically qualify for Serostim;

c. Falsifying testing and result information for qualification of Serostim with the FDA, leading to Medicaid's approval of Serostim as a drug approved for Medicaid reimbursement;

d. Encouraging physicians to order Serostim in quantities that the patients could not consume or did not need;

e. Ordering Serostim under falsified physician signatures or continuing to bill the United States for Serostim under continued prescriptions whtn physicians did not order the prescriptions to continue;

f. Establishing a system encouraging pharmacies to continue to order Serostim even though patients had died or prescriptions had expired;

g. Establishing a system encouraging pharmacies to recruit patients who did not need or did not qualify for Serostim, through which the pharmacies would pay kickbacks to patients and not collect required co-pays;

h. Establishing a system encouraging pharmacies to change prescriptions so that patients received more Serostim than the physician had prescribed for the patient;

i. Having physicians fill out prescription forms in blank for sales representatives to fill in;

j. Conducting tests for physicians to measure body mass wasting, and encouraging physicians to bill Medicaid for those tests that the physicians did not perform.

13. Serostim is a drug prescribed to patients with AIDS and AIDS-related conditions, which according to Serono once taken reduced wasting. Doses of Serostim, however, are extremely expensive, costing upwards of $10,000 per course of treatment, or more. The Medicaid program has approved the prescription of Serostim for AIDs and AIDS-related conditions, and consequently by information and belief. Serono has billed Medicaid tens of millions of dollars for Serostim.

14. Serono had the following "system" for its billings. First, it would send a sales representative to physicians or clinics treating patients with AIDS or AIDS-related conditions. Those sales representatives, using a mechanism that Serono designed ("SOMASCAN," supposedly using "BIA" bio electrical impedence analysis), would "test" the patients, to determine what percentage of their body mass was wasted. If the patient met or was under the

percentage (the "phase angle"), which allowed under Serono and Medicaid guidelines and regulations to allow the physician to prescribe the drug, then, the Serono representative would fill out an order form. The physician then was to sign the form (to confirm that the physician actually had prescribed Serostim as medically necessary), and then the Serono representative would send the form to Serono for the next step of the process.

15. But, Serono sales representatives frequently and regularly manipulated the tests, to show that the patient qualified for Serostim. Consequently, patients who did not qualify to be prescribed Serostim, were prescribed it, contrary Medicaid regulations, to falsely show that the patients should receive Serostim.

16. Further, beginning 1995 when Serono was attempting to have the Food and Drug Administration ("FDA") qualify Serostim for prescription for AIDS and AIDS-related conditions, a Serono sales representative with responsibilities including the Burnside Clinic in South Carolina, gained access to the clinic on the pretense of conducting the trials, and then changed patient morbidity and other records, to show that the drug was effective on those patients, when it had not been; these results were reported to the FDA, which later qualified the drug. Serono also encouraged the representative to get as many patients in the program as possible, many of whom were not actually qualified to receive the drug. The Burnside Clinic discovered the alteration of patient records, and expelled the representative from the clinic.

17. Serono furthered its scheme, by having few physicians sign prescription forms for Serostim. Or, Serono representatives would have physicians sign many, blank forms which the Serono sales representative then filled out. Consequently, in many cases, no physician ever saw the patient prescribed Serostim, for the purposes of the prescription, or actually determined

the prescription medically necessary. Serono presented this system to the physicians as a "service" to allow them escape hiring further staff, to administer the tests and properly supervise the prescription process.

18. In South Carolina and Florida, and by information and belief in other states as well, Serono induced physicians to allow its representatives at the physicians' offices, by "reimbursing" physicians for "doing" tests to determine whether Serostim should be prescribed (the Serono representatives, in fact, did the tests). In other offices, Serono encouraged physicians to bill Medicaid for the tests that Serono representatives did, telling the physician that "if you want to bill for it you can."

19. Serono regularly gave physicians other inducements to physicians, to induce the physicians to allow Serono representatives into the physicians' offices. Serono paid "honoraria" for fictitious "speaking engagements" for physicians - - where no speaking was done - - in New Jersey, Missouri and South Florida; Dr. Thomas Powell and a Dr. Corazone were two New Jersey physicians who received such an inducement. Ray Hudgins, a Serono sales representative, would pay a kickback to nutritionists who recommended Serostim.

20. Mark Sirockman – Regional Manger/director of Serono, told sales representatives, "I don't care if you have to walk through hospital with $100 bills hanging out of your pocket," and that the representatives were to pay whatever inducements were necessary, to get physicians and nutritionists to prescribe Serostim.

21. Serono's "prescription" and billing process allowed Serono sales representatives extreme leeway in determining who received Serostim, and more often than not, if a patient was presented to the representative, the patient would get a prescription. That was because, the

Serono testing mechanism allowed the representative to manipulate test scores, to show, falsely, that the patient qualified for the treatment. So, patients who were not wasting, or wasting sufficiently to qualify for a Serostim prescription, received a prescription anyway. This was in violation of the Medicaid guidelines, for prescription of Serostim.

22. The next step in the process was presentation of claims for payment, and dispensing of Serostim. Serono had a "network" of pharmacies, through which it had arrangements to dispense Serostim; a patient could only go to these pharmacies to get a Serostim prescription filled. The Serono representative would fax the completed forms to Serono's billing office, in Massachusetts. From that office, Serono would issue a bill to Medicaid and instructions to one of its pharmacies, to dispense. The patient would then go to the pharmacy, and be dispensed Serostim; neither the patient, pharmacy nor physician would be involved in the billing.

23. Serono would also regularly increase the milligram dosage, of Serostim that the patients were prescribed, from the "orders" that the physicians (through representatives) submitted to Serono's "medical reimbursement team" in Massachusetts. Relators believe that Jay Mohr (Vice Presidnt at the time of the Serostim Sales Marketing business unit) directed the "team" that if a patient was prescribed 4-5 milligrams of Serostim, for example, to send through 6 milligrams of Serostim (even though Serostim is prescribed by the weight of the patient; the "marketing" side of Serono was in essence falisifying patient weights, in order to increase dosage amounts). As the result patients would receive more Serostim than they should have received, if properly dosed (even according to the manipulated figures coming from Serono sales representatives).

24. But, in come cases, patients did not pick up their prescription; Serono billed Medicaid billed Medicaid even though no prescription was filled. The course of therapy was 12 weeks; the average dose cost was $252 per day. Serono also billed Medicaid for a repeat course of treatment for many patients, although physicians had never ordered the repeat course; Serono simply ordered repeat treatments, as a matter of course. By the time of repeat treatment, it was more likely that the prescription was not picked up, because of the death of the patients.

25. A variation of these frauds existed in South Florida, where Serono pharmacies paid patients, to be prescribed Serostim and have a repeat course of treatment. For initial treatments, these pharmacies would pay the patients $300, and then for repeat treatments, $150. Many times the patients did not pick up their prescriptions; they did pick up the money. The pharmacies, and Serono, were paid by Medicaid in either event.

26. Serono encouraged its pharmacies to go out and "recruit" patients, and send them to clinics where Serono representatives were working. Because of the close-knit nature of the patient population, such "recruitment" was relatively easy, combined with, the kickbacks, and non-collection of co-pays, that the pharmacies extended to patients. Serono would encourage this by paying a kickback to the pharmacies, based on the volume of Serostim that they sold. At the same time, Serono incented pharmacies to "recruit" by requiring them, in order to keep the Serono account, to sell at least $500,000 of Serostim yearly.

27. Serono also paid bonuses to pharmacies based on their refill rates, and imposed a re-fill goal on pharmacies of 90%. Most all pharmacies met that goal.

28. A further variation by pharmacies, done with Serono's knowledge, was that Serono would bill for a 14 week course of treatment, and pay the pharmacy for dispensing 14

weeks' worth of treatment quantity for the drug, but with Serono's knowledge, the pharmacy would only dispense a 12 week course, but keep the payment for the two additional weeks. This would "reimburse" the pharmacies for the co-pay, that many patients were supposed to, but did not pay. Serono did not require patients to pay co-pays, and its pharmacies followed the same procedure.

29. Generally, Serono's procedure was to instruct its sales representatives to do (printed on a key chain that Serono management distributed to representatives), "Whatever it Takes."

**COUNT ONE**

**(31 U.S.C. § 3729 (a)(1), False Claims Act)**
**(Knowingly Presenting a False or Fraudulent Claim)**

30. Plaintiff repeats and realleges the foregoing paragraphs.

31. By virtue of the acts described above, defendants have knowingly presented, or caused to be presented, to officers, employees or agents of the United States Government, false or fraudulent claims for payment or approval. Defendants knew that these claims for payment were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard for whether said claims were true or false. These claims were, therefore, false or fraudulent claims submitted for payment or approval to the United States in violation of in violation of 31 U.S.C. §3729 (a)(1).

32. Plaintiff, the United States, unaware of the foregoing circumstances and conduct of defendants, and in reliance on the accuracy of said false and fraudulent claims, made payments to defendants pursuant to defendants' false or fraudulent claims, in particular, paying to the

defendants policy commission, administrative, and related fees, in an amount to be established at trial or on motion.

**COUNT TWO**

**(31 U.S.C. § 3729 (a)(2), False Claims Act)**
**(Knowingly Making, Using or Causing to be Made or Used, a False Record or Statement to Get a False or Fraudulent Claim Paid or Approved by the Government)**

33. Plaintiff repeats and realleges the foregoing paragraphs.

34. By virtue of the acts described above, defendants have knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Government. Defendants had actual knowledge that the submissions made to the Medicaid program, including, that defendants were complying with Medicaid regulations governing the prescription of and reimbursement for Serostim, that defendants were causing co-pays to be paid, and that defendants were not paying inducements for the prescription of Medicaid, all detailed above, contained certifications that were false, or they were deliberately ignorant of and acted in reckless disregard for whether such claims were true or false, in violation of 31 U.S.C. § 3729(a)(2).

35. Plaintiff, the United States, unaware of the foregoing circumstances and conduct of defendants, and unaware of the falsity of the records and or statements made, used or caused to be made or used by defendants, and in reliance on the accuracy thereof, paid the false or fraudulent claims submitted to it which resulted in the United States being damaged, in an amount to be established at trial or on motion.

**COUNT THREE**

**31 U.S.C. § 3729 (a)(3), False Claims Act)**
**(Knowingly Engaging in a Conspiracy in Violation of the False Claims Act)**

36. Plaintiff repeats and realleges the foregoing paragraphs.

37. Serono, SI, and SG, as a part of the illegal conduct and illegal business and financial arrangements, combined and conspired to obtain payments wrongfully from the United States by obtaining or seeking to obtain allowance and payment of false or fraudulent claims in violation of 31 U.S.C. §3729(a)(3).

38. As a result of this illegal conspiracy, plaintiff United States, suffered substantial damages in an amount to be determined at trial or on motion.

**COUNT FOUR**

**(Payment Under Mistake of Fact)**

39. Plaintiff repeats and realleges the foregoing paragraphs.

40. The United States made payments on claims submitted by, or on behalf of defendant Serrono, under the erroneous belief that the records that defendans submitted to it met the requirements and regulations of tMedicaid and that the Government was indeed paying what it had contracted to pay. The beliefs of the United States were material to the amount of payments made by the United States.

41. The United States would not have entered into the contracts without defendants' false representations, as set out above.

42. As a result of overpayment described above, plaintiff United States is entitled to recover damages in an amount to be determined.

**COUNT FIVE**

**(Unjust Enrichment- - Constructive Trust)**

43. Plaintiff repeats and realleges the foregoing paragraphs.

44. Defendants were unjustly enriched as set out above.

45. As a result of overpayment described above, plaintiff United States is entitled to recover damages in an amount to be determined.

**PRAYER FOR RELIEF**

WHEREFORE, on behalf of the United States Government and themselves, Relators demand judgment against defendants as follows:

a. That by reason of the violations of the False Claims Act as set out in the First through Fourth Causes of Action, this Court enter judgment against Defendants in an amount up to three (3) times the amount of damages the United States Government has sustained because of defendants' actions, plus a civil penalty of not less than Five Thousand Dollars ($5,000,00) and not more than Ten Thousand Dollars ($10,000.00) for each violation of 31 U.S.C. §3729, and by reason of the remaining causes of action, that the Court enter judgment against Defendants in amount of the actual damages to the United States, all plus interest and costs;

b. That Relators as Qui Tam plaintiffs be awarded the maximum amount allowed pursuant to Section 3730(d) of the False Claims Act and/or any other applicable provision of law;

c. That Relators be awarded all costs of this action, including attorneys' fees and court costs pursuant to Section 3730(h) of the False Claims Act;

d. That Relators be awarded their expenses in connection with this action pursuant to

31 U.S.C. Section 3729.

f. That Relators receive such other and further relief as the Court may deem to be just and proper.

**JURY DEMAND**

Pursuant to Fed. R. Civ. P. 38 (b), Relators, on their on behalf and on behalf of the United States, hereby demand a trial by jury on all issues so triable.

Dated: September 21, 2000.

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